

Atty Dkt No. 6200-0013
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1. (Amended) A pharmaceutical composition for oral administration of fenofibrate comprising:

- a) a therapeutically effective amount of fenofibrate; and
- b) a solubilizer comprising a vitamin E substance wherein the ratio of the fenofibrate to the vitamin E substance is less than or equal to 0.305 mg/IU.

3. (Amended) The pharmaceutical composition of claim 1, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

5. (Amended) The pharmaceutical composition of claim 54, wherein said solubilizer is a trialkyl citrate.

8. (Amended) The pharmaceutical composition of claim 54, wherein said solubilizer is a lactone.

10. (Amended) The pharmaceutical composition of claim 54, wherein said solubilizer is a nitrogen-containing solvent.

37. (Amended) The pharmaceutical composition of claim 1, in a liquid form.

38. (Amended) The pharmaceutical composition of claim 1, in a semi-liquid form.

39. (Amended) The pharmaceutical composition of claim 1, wherein the fenofibrate is at least 50% solubilized in said composition.

40. (Amended) The pharmaceutical composition of claim 39, wherein the fenofibrate is at least 75% solubilized in said composition.

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41. (Amended) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 1.

42. (Amended) The pharmaceutical dosage form of claim 54, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

43. (Amended) The pharmaceutical dosage form of claim 54, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

46. (Amended) The pharmaceutical composition of claim 1, wherein the fenofibrate is completely solubilized in said composition.

47. (Amended) The pharmaceutical dosage form of claim 42, wherein at least about 40 mg of the fenofibrate is solubilized.

48. (Amended) The pharmaceutical dosage form of claim 43, wherein at least about 67 mg of the fenofibrate is solubilized.

49. (Amended) The pharmaceutical dosage form of claim 48, wherein at least about 100 mg of the fenofibrate is solubilized.

50. (Amended) A pharmaceutical composition for administration of a hydrophobic drug comprising:

- (a) a therapeutically effective amount of a hydrophobic drug; and
- (b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, the vitamin E substance is present in an amount of from about 1 to 99 % w/w of said composition, and the hydrophobic drug is selected from the group consisting of hydrophobic drugs that have not been

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micronized and hydrophobic drugs that have been micronized in the absence of a solid surfactant.

51. (Amended) A method for treating a patient suffering from a fenofibrate-responsive condition, disease or disorder, comprising administering to the patient a therapeutically effective amount of any one of claims 1, 54 or 69.

Also add new claims 52-102 as indicated in Appendix A. The new claims are as follows:

52. The pharmaceutical composition of claim 1, wherein the ratio of the fenofibrate to the solubilizer is less than or equal to 0.182 mg/IU.

53. The pharmaceutical dosage form of claim 41, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

54. A pharmaceutical composition for oral administration of fenofibrate, comprising:

- a) a therapeutically effective amount of fenofibrate; and
- b) an effective solubilizing amount of a solubilizer selected from the group consisting of a trialkyl citrate, a lactone, a nitrogen-containing solvent, and combinations thereof.

55. The pharmaceutical composition of claim 54, in a liquid form.

56. The pharmaceutical composition of claim 54, in a semi-liquid form.

57. The pharmaceutical composition of claim 54, wherein the fenofibrate is at least 50% solubilized in said composition.

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58. The pharmaceutical composition of claim 57, wherein the fenofibrate is at least 75% solubilized in said composition.

59. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 54.

60. The pharmaceutical dosage form of claim 59, wherein the therapeutically effective amount of fenofibrate is a unit dosage.

61. The pharmaceutical dosage form of claim 60, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.

62. The pharmaceutical dosage form of claim 61, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.

63. The pharmaceutical dosage form of claim 59, in capsule form.

64. The pharmaceutical dosage form of claim 59, in the form of a drink.

65. The pharmaceutical composition of claim 54, wherein the fenofibrate is completely solubilized in said composition.

66. The pharmaceutical dosage form of claim 61, wherein at least about 40 mg of the fenofibrate is solubilized.

67. The pharmaceutical dosage form of claim 62, wherein at least about 67 mg of the fenofibrate is solubilized.

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68. The pharmaceutical dosage form of claim 63, wherein at least about 100 mg of the fenofibrate is solubilized.

69. A pharmaceutical composition for oral administration of fenofibrate comprising:

a) a therapeutically effective amount of a hydrophobic drug selected from the group consisting of fenofibrate that has not been micronized and fenofibrate that has been micronized in the absence of a solid surfactant; and

b) a solubilizer comprising a vitamin E substance, a trialkyl citrate, a lactone, a nitrogen-containing solvent or combination thereof; and

c) an optional solid surfactant.

70. The pharmaceutical composition of claim 69, wherein the fenofibrate has not been micronized.

71. The pharmaceutical composition of claim 69, wherein the fenofibrate has been micronized in the absence of a solid surfactant.

72. The pharmaceutical composition of claim 69, wherein said solubilizer is a vitamin E substance.

73. The pharmaceutical composition of claim 72, wherein said vitamin E substance is selected from the group consisting of tocopherols, tocopherol derivatives with organic acids, tocotrienols and mixtures thereof.

74. The pharmaceutical composition of claim 73, wherein said vitamin E substance is selected from the group consisting of alpha tocopherol, alpha tocopheryl acetate, alpha tocopheryl acid succinate, alpha tocopherol polyethylene glycol 1000 succinate and mixtures thereof.

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75. The pharmaceutical composition of claim 74, wherein said solubilizer is a trialkyl citrate.

76. The pharmaceutical composition of claim 75, wherein said trialkyl citrate is selected from the group consisting of triethyl citrate, acetyltriethyl citrate, tributyl citrate, acetyltributyl citrate and mixtures thereof.

77. The pharmaceutical composition of claim 76, wherein said trialkyl citrate is triethyl citrate.

78. The pharmaceutical composition of claim 69, wherein said solubilizer is a lactone.

79. The pharmaceutical composition of claim 78, wherein said lactone is selected from the group consisting of ϵ -caprolactone and isomers thereof, δ -valerolactone and isomers thereof and β -butyrolactone and isomers thereof and mixtures thereof.

80. The pharmaceutical composition of claim 69, wherein said solubilizer is a nitrogen-containing solvent.

81. The pharmaceutical composition of claim 80, wherein said nitrogen-containing solvent is selected from the group consisting of dimethylformamide, dimethylacetamide, N-alkylpyrrolidone, N-hydroxyalkylpyrrolidone, N-alkylpiperidone, N-alkylcaprolactam and mixtures thereof.

82. The pharmaceutical composition of claim 81, wherein said solubilizer is selected from the group consisting of N-methyl 2-pyrrolidone, N-ethyl 2-pyrrolidone and mixtures thereof.

83. The pharmaceutical composition of claim 69, in a liquid form.

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84. The pharmaceutical composition of claim 69, in a semi-liquid form.
85. The pharmaceutical composition of claim 69, wherein the fenofibrate is at least 50% solubilized in said composition.
86. The pharmaceutical composition of claim 85, wherein the fenofibrate is at least 75% solubilized in said composition.
87. A pharmaceutical dosage form comprising the pharmaceutical composition of claim 71.
88. The pharmaceutical dosage form of claim 86, wherein the therapeutically effective amount of fenofibrate is a unit dosage.
89. The pharmaceutical dosage form of claim 88, wherein the unit dosage of fenofibrate is from about 40 mg to about 250 mg.
90. The pharmaceutical dosage form of claim 89, wherein the unit dosage of fenofibrate is from about 67 mg to about 200 mg.
91. The pharmaceutical dosage form of claim 87, in capsule form.
92. The pharmaceutical dosage form of claim 87, in the form of a drink.
93. The pharmaceutical composition of claim 69, wherein the fenofibrate is completely solubilized in said composition.

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94. The pharmaceutical dosage form of claim 89, wherein at least about 40 mg of the fenofibrate is solubilized.

95. The pharmaceutical dosage form of claim 90, wherein at least about 67 mg of the fenofibrate is solubilized.

96. The pharmaceutical dosage form of claim 95, wherein at least about 100 mg of the fenofibrate is solubilized.

97. The method of claim 51, wherein the fenofibrate-responsive condition, disease or disorder is a lipid disorder.

98. The method of claim 97, wherein the lipid disorder is an above-normal level of cholesterol.

99. The method of claim 97, wherein the lipid disorder is an above-normal triglyceride level.

100. The method of claim 97, wherein the lipid disorder is a below-normal level of high density lipoproteins.

101. A pharmaceutical composition for administration of a hydrophobic drug comprising:

- (a) a therapeutically effective amount of a hydrophobic drug; and
- (b) a vitamin E substance,

wherein the hydrophobic drug is present in an amount of from about 0.1 to 30 % w/w of the composition and is at least about 50% solubilized in the composition, and the ratio of the hydrophobic drug to the vitamin E substance is less than or equal to 0.305 mg/IU.